



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: James Ronald Lawter

Serial No.: 10/601,259

Art Unit: Not Yet Assigned

Filed: June 20, 2003

Examiner: Not Yet Assigned

For: *RAPIDLY DISINTEGRATING FORMULATIONS FOR TREATING OR PREVENTING MUCOSITIS*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicant submits an Information Disclosure Statement, including five (5) pages of Form PTO-1449 and copies of the forty-five (45) documents cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
3,966,808	06-29-1976	Luciano	260/559
4,754,597	07-05-1988	Buxton, et al.	53/440
4,961,926	10-09-1990	Gabrilove	424/85.1
5,046,618	09-10-1991	Wood	206/532

5,082,653	01-21-1992	Pan, et al.	424/54
5,102,870	04-07-1992	Florine, et al.	514/12
5,188,825	02-23-1993	Iles, et al.	424/78.1
5,284,963	02-08-1994	Sum, et al.	552/205
5,328,902	07-12-1994	Sum, et al.	514/152
5,343,672	09-06-1994	Kearney, et al.	53/440
5,358,118	10-25-1994	Thompson, et al.	206/538
5,386,041	01-31-1995	Sum, et al.	552/205
5,401,729	03-28-1995	Sum, et al.	514/152
5,420,272	05-30-1995	Sum, et al.	544/63
5,430,162	07-04-1995	Sum, et al.	552/205
5,545,668	08-13-1996	Skubitz, et al.	514/561
5,558,880	09-24-1996	Gole, et al.	424/484
5,576,014	11-19-1996	Mizumoto, et al.	424/435
5,631,023	05-20-1997	Kearney, et al.	424/465
5,635,489	06-03-1997	Haley	514/21
5,648,093	07-15-1997	Gole, et al.	424/484
5,729,958	03-24-1998	Kearney, et al.	53/440
5,827,541	10-27-1998	Yarwood, et al.	424/489
5,837,287	11-17-1998	Yarwood, et al.	424/484
5,886,175	03-23-1999	Sum, et al.	544/63
5,945,089	08-31-1999	Libin	424/54
5,981,499	11-09-1999	Hau	514/29
6,024,981	02-15-2000	Khankari, et al.	424/464
6,025,326	02-15-2000	Steinberg, et al.	514/2
6,156,339	12-05-2000	Grother, et al.	424/450
6,221,392	04-24-2001	Khankari, et al.	424/464
6,316,027	11-13-2001	Johnson, et al.	424/464

Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
WO 99/45910	09-16-1999	Mucosal Therapeutics, Inc.	PCT
WO 01/19362	03-22-2001	Orapharma, Inc.	PCT

Publications

BARKER, et al., "Oral care with vancomycin paste for reduction in incidence of alpha-hemolytic streptococcal sepsis," *J Pediatr Hematol Oncol* 17(2): 151-55 (1995).

BELLM, et al., "Assessment of various topical oral formulations by bone marrow transplant recipients," *Oral Oncology* 37: 42-49 (2001).

EPSTEIN & WONG, "The efficacy of sucralfate suspension in the prevention of oral mucositis due to radiation therapy," *Int. J. Radiat. Oncol. Biol. Phys.* 28(3): 693-98 (1994).

KOROLKAVAS & BURCKHALTER, eds., Essentials of Medicinal Chemistry, John Wiley and Sons, Inc.: New York, p. 512-517 (1976).

LOPRINZI, et al., "Alleviation of cytotoxic therapy-induced normal tissue damage," *Sem. Oncol.* 22(2) Suppl. 3:95-97 (1995).

MITSCHER, et al., "Quinolone antimicrobial agents. 1. Versatile new synthesis of 1-alkyl-1,4-dihydro-4-oxo-3-quinolinecarboxylic acids," *J. Med. Chem.* 21(5):485-9 (1978).

ROTHWELL & SPEKTOR, "Palliation of radiation-related mucositis," *Special Care in Dentistry* 10(1):21-25 (1990).

SONIS, "Oral Complications in Cancer Therapy," in Principles and Practice of Oncology, vol. 2 (De Vitta et al., eds.) J.B. Lippincott Co.: Philadelphia, p. 2385-2394 (1993).

SONIS, "Oral Complications," in Gastrointestinal Complications, Lea & Febiger: Philadelphia, p. 2381-2388 (1993).


SPIJKERVET, et al., "Chlorhexidine inactivation by saliva," *Oral Surg. Oral Med. Oral Pathol.* 69(4):444-49 (1990).

VERDI, et al., "A double-blind, randomized, placebo-controlled, crossover trial of pentoxifylline for the prevention of chemotherapy-induced oral mucositis," *Oral Surg. Oral Med. Oral Pathol. Oral Radiol. Endod.* 80(1):36-42 (1995).

Remarks

. This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicant invites the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicant is of the opinion that his claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

Dated: September 4, 2003

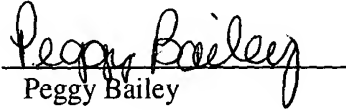
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U.S.S.N.: 10/601,259
Filed: June 20, 2003
INFORMATION DISCLOSURE STATEMENT

Certificate of Mailing under 37 C.F.R. § 1.8(a)

I hereby certify that this Information Disclosure Statement, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: September 4, 2003


Peggy Bailey

ATL1 #591808 v1

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<p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>		Complete If Known	
		Application Number	10/601,259
		Filing Date	June 20, 2003
		First Named Inventor	James Ronald Lawter
		Group Art Unit	
		Examiner Name	
Sheet 1 of 5	Attorney Docket Number	ORA 104	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		3,966,808		Luciano	06-29-1976	
		4,754,597		Buxton, et al.	07-05-1988	
		4,961,926		Gabrilove	10-09-1990	
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		5,082,653		Pan, et al.	01-21-1992	
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		5,188,825		Iles, et al.	02-23-1993	
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		5,343,672		Kearney, et al.	09-06-1994	
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		5,401,729		Sum, et al.	03-28-1995	
		5,420,272		Sum, et al.	05-30-1995	
		5,430,162		Sum, et al.	07-04-1995	

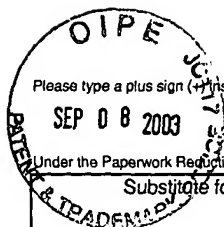
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		Office. ⁴	Number ⁴	Kind Code ⁵ (if known)				
		PCT	WO 99/45910		Mucosal Therapeutics, Inc.	09-16-1999		
		PCT	WO 01/19362		Orapharma, Inc.	03-22-2001		

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		5,631,023		Kearney, et al.	05-20-1997	
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		5,981,499		Hau	11-09-1999	
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		6,025,326		Steinberg, et al.	02-15-2000	
		6,156,339		Grother, et al.	12-05-2000	

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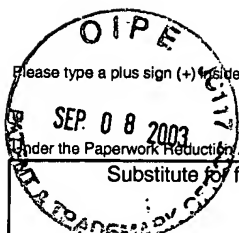
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OTHER ART -- NON PATENT LITERATURE DOCUMENTS

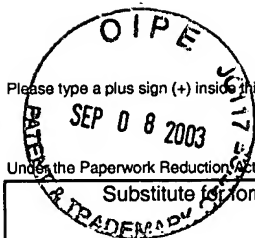
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	/	BARKER, et al., "Oral care with vancomycin paste for reduction in incidence of alpha-hemolytic streptococcal sepsis," <i>J Pediatr Hematol Oncol</i> 17(2): 151-55 (1995).	
	/	BELLM, et al., "Assessment of various topical oral formulations by bone marrow transplant recipients," <i>Oral Oncology</i> 37: 42-49 (2001).	
	/	EPSTEIN & WONG, "The efficacy of sucralfate suspension in the prevention of oral mucositis due to radiation therapy," <i>Int. J. Radiat. Oncol. Biol. Phys.</i> 28(3): 693-98 (1994).	
	/	KOROLKAVAS & BURCKHALTER, eds., <u>Essentials of Medicinal Chemistry</u> , John Wiley and Sons, Inc.: New York, p. 512-517 (1976).	
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Group Art Unit	
Examiner Name	
Attorney Docket Number	ORA 104

Sheet 5 of 5

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		VERDI, et al., "A double-blind, randomized, placebo-controlled, crossover trial of pentoxifylline for the prevention of chemotherapy-induced oral mucositis," <i>Oral Surg. Oral Med. Oral Pathol. Endod.</i> 80(1):36-42 (1995).	

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